Remarks

The Office Action mailed September 5, 2001 has been received and reviewed. Claims 1-5, 12-15, 19, 27, 28, 30 and 32 are pending in the application. All stand rejected. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

1. Objection under 35 U.S.C. §132

The specification was objected to as allegedly containing new matter. Applicants respectfully traverse this objection. The Examiner alleges that the September 27, 1999 amendment to the specification which inserted the phrase "(purified saponin)" at the end of the sentence: "The preferred adjuvant is Quil A" constitutes new matter. (See, Specification, page 19, line 19). Applicants respectfully submit that this amendment does not constitute new matter.

The Specification discloses that "the vaccine may also contain an aqueous medium or a water containing suspension, often mixed with other constituents in order to increase the activity and/or shelf life. These constituents may be . . . adjuvants to improve the immune response (e.g. . . . saponin)." (Specification, page 19, lines 14-20). Thus, saponins were disclosed as potential adjuvants. Further, it is known in the art that purified quillaja saponin fractions are known as "Quil A." Accordingly, applicants respectfully submit that no new matter was added to the specification by amending the above identified sentence to read "The preferred adjuvant is Quil A (purified saponin)". Reconsideration and withdrawal of the objection is requested.

2. Rejection under 35 U.S.C. §112

Claims 1-5, 12-15, 19, 27, 28, 30 and 32 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention. As more thoroughly described herein, applicants have amended the claim and respectfully traverse the rejection.

Further, claims 1-5, 12-15, 19, 27, 28, 30 and 32 stand rejected under 35 U.S.C. § 112, second paragraph as assertedly being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicants regard as the invention. Applicants have amended the claim and respectfully traverse the rejection.

Applicants have amended claim 1 to recite "wherein said composition consists essentially of proteins which are non-membrane-bound *Eimeria*." Applicants respectfully submit that this amendment is supported by the specification as filed and overcomes the rejection. (See, e.g., Specification, page 4, lines 1-5). Reconsideration and withdrawal of the rejection is requested.

3. Rejection of Claims 1-5, 12-15, 19, 27, 28, 30 and 32 under 35 U.S.C. § 102(b)

Claims 1-5, 12-15, 19, 27, 28, 30 and 32 stand rejected under 35 U.S.C. § 102(b) in view of EP0382531 to Gurnett. This rejection is respectfully traversed. Applicants respectfully submit that Gurnett discloses that the "hydrophobic glycolipid linked proteins" partition into the hydrophilic phase of a Triton X-114 extraction only when lipase is added prior to phase separation. Gurnett describes these otherwise hydrophobic proteins (which partitions into the detergent/ hydrophobic phase in the absence of lipase) as "membrane associated proteins" due to the presence of a glycolipid membrane attachment anchor." Thus, Gurnett discloses membrane-bound proteins which are naturally hydrophobic unless treated with a fat digesting enzyme. (Gurnett, page 9, lines 44-47 and 52-55).

By way of contrast, claim 1 as amended recites "wherein said composition consists essentially of proteins which are non-membrane-bound *Eimeria*." Applicants respectfully submit that this amendment is supported by the specification as filed. (Specification, page 4, lines 1-5). The present invention is not directed toward membrane-bound proteins. (Specification, page 4, lines 1-5). Specifically, the specification discloses that a composition according to the present invention will typically be free of one or more *Eimeria* proteins which occur in *Eimeria* in nature. In one embodiment, the composition will be substantially free of *Eimeria* proteins other than proteins in the hydrophilic phase of a Triton X-114 extract of *Eimeria* sporozoite. As proteins that are membrane-bound in *Eimeria* are hydrophobic, the specification discloses that these membrane-bound may be absent. (Specification, page 4, lines 1-5). Clearly, a composition consisting essentially of non-membrane-bound proteins is not anticipated by Gurnett.

As Gurnett fails to teach or suggest every limitation of claim 1, applicants respectfully submit that claim 1 is not anticipated by Gurnett.

Claims 2 through 5, 12 through 15, 19, 27, 28, 30 and 32 each depend, either directly or indirectly from claim 1 and avoid Gurnett for the same reasons.

4. Rejection of Claims 14 and 28 under 35 U.S.C. § 103(a)

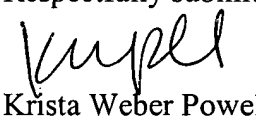
Claims 14 and 18 stand rejected under 35 U.S.C. §103(a) under Gurnett et al. in view of MacKenzie (U.S. Patent 4,981,684) and in further view of Estrada et al. (U.S. Patent 5,597,807).

Claims 14 and 28 depend from claim 1. The Court of Appeals for the Federal Circuit has stated that "dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). *See also,* MPEP § 2143.03. Thus, as claim 1 is not obvious in view of the proposed combination of references, claims 14 and 28 also avoid the proposed combination of references for at least this reason. Reconsideration and withdrawal of the rejection is requested.

Conclusion

In view of the amendments and remarks presented herein, applicants respectfully submit that claims 1-5, 12-15, 19, 27, 28, 30 and 32, are allowable, and an early notice thereof is respectfully solicited. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Krista Weber Powell
Registration No. 47,867
Attorney for Applicants
TRASK BRITT, PC
P. O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: (801) 532-1922

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Attachment: Marked up version of the amended claims

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended five times) A composition free of whole *Eimeria* [parasite] parasites, which comprises one or more proteins, of fragments thereof, wherein said proteins:

(a) are present in the hydrophilic phase of a [Triton X-114 (]tertoctylphenoxypoly (ethoxyethanol)[)] extract of *Eimeria* [sporozoite] sporozoites; and

(b) have molecular masses of 26-30 kDa ± 5 kDa when determined by SDS-PAGE under reducing conditions;

and wherein said composition [is substantially free] consists essentially of proteins which are non-membrane-bound in *Eimeria*.

2. (Amended) [A] The composition according to claim 1, wherein said extract of *Eimeria* sporozoites is an extract of *E. tenella, E. acervulina. E. maxima, E. brunetti, E. necatrix* or *E. mitis* sporozoites.

3. (Amended three times) [A] The composition according to claim 1, wherein at least 50% w/w of proteinaceous material present is made up of one or more of said proteins and/or fragments.

4. (Amended three times) [A] The composition according to claim 1, wherein a plurality of said proteins, and/or fragments or variants thereof are present.

5. (Amended three times) [A] The composition according to claim 1, wherein only one of said proteins or fragments thereof is present.

13. (Amended three times) [A] The vaccine composition according to claim 12, wherein said vaccine comprises an adjuvant.

14. (Amended four times) [A] The composition according to claim 13, wherein the adjuvant is Quil A.

15. (Amended twice) [A] The vaccine composition according to claim 12, which is in unit dosage form.

27. (Amended) [A] The vaccine composition according to claim 13, which is in unit dosage form.

28. (Amended) [A] The vaccine composition according to claim 14, which is in unit dosage form.